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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/210,995	12/15/1998	SHEENA M. LOOSMORE	1038-844MIS:	7731

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/22/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/210,995

Applicant(s)

LOOSMORE ET AL

Examiner

Ja-Na A Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 6-24 are under consideration in the action.

Response to Arguments

2. Applicant's arguments filed July 24, 2002 have been fully considered but they are not persuasive.

Claims 6-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barenkamp et al., (WO 97/36,914) in view of Loosmore et al. (US Patent 5,506,139). The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The rejection was on the grounds that it would have been obvious at the time of applicant's invention to have an immunogenic composition to confer protection against *Haemophilus influenzae* comprising at least two different antigens, wherein one is a heat shock protein as taught by Loosmore et al., and the other is a high molecular weight adhesin protein, HMW1 or HMW2 which is an important protective antigen as taught by Barenkamp et al., (WO 97/36,914), because Loosmore et al., teach that analogs of Hin47 with reduced protease activity from *Haemophilus influenzae* are useful in vaccination against diseases caused by *H. influenzae* or other bacterial pathogens and these proteins are capable of eliciting protective opsonizing or bactericidal antibodies.

Applicant's urge that there is no suggestion that to combine the references since the Barenkamp et al., lack a specific teaching to combine the mutant Hin47 protein with

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the High Molecular Weight (HMW) protein in an immunogenic composition. This argument is not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, it would have been obvious at the time of appellant's invention to have an immunogenic composition to confer protection against *Haemophilus influenzae* comprising at least two different antigens, where one is a well known high molecular weight adhesin protein, HMW1 or HMW2, which are important protective antigens that should comprise one component of a multi-component non-typeable *H. influenzae* vaccine as taught by Barenkamp et al., (WO 97/36,914), in combination with the analog of Hin47 which is a non-proteolytic heat shock protein with substantially reduced proteolytic activity useable in other immunogenic preparations as taught by Loosmore et al.

Furthermore, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re

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Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious). See In re Geiger, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987) ("Based upon the prior art and the fact that each of the three components of the composition used in the claimed method is conventionally employed in the art for treating cooling water).

In this case, no more than routine skill was required at the time of appellants invention to combine two well known antigens of *H. influenzae*, an adhesin and a heat shock protein, since the prior art shows that both: elicit an immunogenic response in a host; provide protection against a *H. influenzae* infection; and are useful in immunogenic composition in combination with other immunostimulating antigens. Accordingly, both antigens are useful for the same purpose, to form an immunogenic composition to be used for that very same purpose. Thus, applicant's argument is unpersuasive.

Applicant argues that there is no motivation provided from the disclosure of Barenkamp et al., to select the non-proteolytic analog of Hin47 protein of Loosmore et al., and there is no motivation to select the non-proteolytic analog of Hin47 for the purpose that the appellants make the selection and again, this argument is not persuasive.

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). The synergy concept is a well established in the art and it would require no more than routine skill to utilize two well-known components that have similar purpose and are capable of achieving similar results in a single composition as instantly claimed. Furthermore, it would have been prima facie obvious to one of skill in the art at the time of appellant's invention to have an immunogenic composition to confer protection against *Haemophilus influenzae* comprising at least two different antigens, wherein one is a heat shock protein as taught by Loosmore et al., and the other is a high molecular weight adhesin protein, HMW1 or HMW2 which is an important protective antigen as taught by Barenkamp et al., (WO 97/36,914), because Loosmore et al., teach that analogs of Hin47 elicit an immune response capable of producing anti-Hin47, opsonizing or bactericidal antibodies, and provides data that shows Hin47 analogs provide protective ability.

As previously stated, it would have been obvious at the time of applicant's invention to have an immunogenic composition to confer protection against *Haemophilus influenzae* comprising at least two different antigens, where one is a high molecular weight adhesin protein, HMW1 or HMW2, since Barenkamp et al. (WO 97/36,914), teach that adhesin proteins are important protective antigens which should comprise one component of a multi-component non-typeable *H. influenzae* vaccine and the other component as taught by Loosmore et al., is an analog of Hin47 because the Hin47 analog can be used as a component in an immunogenic composition and can elicit anti-Hin47, opsonizing or bactericidal antibodies to provide an immunogenic response to *H. influenzae*. Furthermore, one would expect a reasonable level of success by combining the well-known HMW adhesin proteins and the well known Hin47 analogs in a multi-component immunogenic composition since both Barenkamp et al., (WO 97/36,914) and Loosmore et al., teach the use of these antigens in immunogenic compositions against *Haemophilus influenzae*. Thus applicant's argument is not persuasive.

Applicant argues that there are important considerations when combining antigens in an immunogenic composition may be the possibility of impairing or adversely affecting the respective immunogenicities; and applicant's results could not have been predicted in advance from the information provided in Barenkamp et al, and Loosmore et al.

In response to applicant's arguments, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). One of ordinary skill would expect a reasonable level of success by combining the well known HMW adhesin proteins and the well known Hin47 analogs in a multi-component immunogenic composition since both Barenkamp et al., (WO 97/36,914), and Loosmore et al., teach the use of these antigens in immunogenic compositions against *Haemophilus influenzae* infection. No more than routine skill would have been required when both Barenkamp et al., (WO 97/36,914), and Loosmore et al., teach the additional use of adjuvants; the addition of antigenic components; and methods for immunizing a host against disease caused by an infection with *H. influenzae* comprising administration of different antigens of *H. influenzae* in an immunogenic composition.

Applicant argues that they have shown unexpected results. However, applicant sets forth statements drawn to synergistic effects that can be achieved in both response to the rHMW and H91A Hin47 when in combination. There is no proof of unexpected results, synergistic results are not proof of unexpected results. Therefore the argument is unpersuasive.

Applicant argues that there is no indication that Barenkamp et al., teach that adhesin proteins are potentially important protective antigens that should comprise one component of a multi-component non-typeable *H. influenzae* vaccine.

However, it is the examiner's position that Barenkamp et al., teach an immunogenic composition comprising a HMW protein and at least one other immunogenic or immunostimulating material and at least one adjuvant (page 7 lines 1-5). Barenkamp et al., (WO 97/36,914), teach complexing additional components to the antigenic composition to enhance immune response including herpes simplex virus vaccine, pseudorabies virus vaccine, tetanus toxoid, poliomyelitis virus vaccine, hepatitis B virus antigen and others (page 24-25 lines 7-10). Finally, Barenkamp et al's., (WO 97/36,914) data teach that HMW adhesin proteins are potentially important protective antigens that may comprise one component of a multi-component NTHI (non-typeable *H. influenzae*) vaccine (page 49 lines 15-19). Thus, applicant's argument is not persuasive.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines *JAH*

October 16, 2002


MARK NAVARRO
PRIMARY EXAMINER